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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,223	05/07/1999	JUDITH A. VARNER	6627-PA11	4575

7590 02/26/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/26/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/307,223

Applicant(s)
Varner et al

Examiner
Ungar

Art Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 25, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9-14, 19, 20, 55-72, 75, and 80-123 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-14, 19, 20, 55-72, 75, and 80-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 23 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2002 (Paper No. 22) has been entered. Claims 121-123 were added, Claims 1, 2, 13, 19, 55, 57, 65-67, 70-72, 75, 80, 82, 84, 86, 90, 92, 94, 96, 106, 108, 110, 112, 114, 116-117, 119 were amended. Claims m1-5, 9-14, 19-20, 55-72, 75 and 80-123 are currently under prosecution.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are maintained:

Claim Rejections - 35 USC § 112

4. Claim 2 remains rejected under 35 USC 112, second paragraph for the reasons previously set forth in Paper No. 17, Section 4, pages 2-3.

Applicant (a) reiterates previous arguments, (b) argues that the Wood's Declaration has not been properly considered and since Dr. Woods understands the meaning of the term "substantially" after reading the specifically referred to mathematical ranges recited in the Specification and is qualified to speak on the level of ordinary skill, the rejection should be withdrawn, (c) Examiner has not provided any technical evidence to rebut Dr. Woods' Declarations, (d) if the meaning of a claim is discernible, the claim is definite. The arguments and the Woods Declaration have been considered but have not been found persuasive (a')

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for the reasons previously set forth, (b') as previously disclosed, the term "substantially" is a relative term, in the absence of an art recognized definition of the term, the metes and bounds of the claim cannot be determined and the claim is indefinite since the claim is not limited to the mathematical ranges recited in the Specification. The rejection may be obviated by amending claim 2, for example, to recite the mathematical ranges recited in the Specification, (c') in the absence of an art recognized definition of the term "substantial" it is not clear how technical evidence would be relevant to the instant rejection, (d') for the reasons set forth previously and above, the meaning of the claim is not discernible. Applicant's arguments have not been found persuasive and the rejection is maintained.

5. Claims 80-86, 90-96 and 110-116 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 17, Section 5, page 3.

Applicant (a) reiterates previous arguments, (b) argues that the Wood's Declaration has not been properly considered and that Dr. Woods, concludes from page 18, lines 7-15, page 19, lines 24-27, and page 23, lines 5-14 that the written description requirement is satisfied, (c) no technical evidence has been advanced by the Examiner to rebut Dr. Woods' Declaration, (d) the written description requirement is satisfied if the disclosure by Applicant conveys with reasonable clarity that, as of the time of the filing date sought, he or she was in possession of the claimed invention. The arguments and the Woods Declaration have been considered but have not been found persuasive because although Applicant has amended the claims to substitute the term "antagonist" for the term "agent", the issues remain the same, that is that there is no support for the claimed limitations

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and further (a') for the reasons previously set forth, (b') the Declaration's disclosure of the subject matter on pages 18, 19 and 23 does not provide support for the broadly written language drawn to antagonist fold binding since only antibody binding is supported by the specification, (c') in the absence of support in the specification for the claims as written, it is not clear how technical evidence would be relevant to the instant rejection, (d') for the reasons set forth previously and above, the disclosure does not convey with reasonable clarity that, as of the time of the filing date sought, he or she was in possession of the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained.

6. Claims 86, 96 and 116 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 17, Section 6, page 4.

Applicant (a) reiterates previous arguments and the arguments set forth above drawn to the previous rejection. The arguments have been considered but have not been found persuasive for the reasons set forth previously and above even though Applicant has amended the claims to substitute the term "antagonist" for the term "agent", the issues remain the same, that is that there is no support for the claimed limitations. Applicant's arguments have not been found persuasive and the rejection is maintained.

7. Claims 80-120 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in paper No. 17, Section 7, pages 4-7.

Applicant argues that (a) Ruoshahti et al's data is irrelevant because the invention is drawn to epithelial, not endothelial cells, (b) Ruoslahti et al does not

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teach or suggest that peptide binding affinity to alpha5B1 integrin that is less than 100-fold greater than to another integrin is inoperable, (c) Applicant incorporates and reiterates previous arguments. The arguments have been considered but have not been found persuasive because (a') the state of the art demonstrates the requirement for selectivity for binding to alpha5B1 integrin. It is clear, given the ubiquitous identity of the integrin and known agonists thereto that it would be expected that selectivity of binding would be the same, regardless of cell type, (b') as previously noted, for the reasons previously set forth, without selectivity, the invention is not enabled, (c') the arguments are not persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

8. Claims 1-5, 9-13, 55-66, 68-69, 71-72, 75 and 80-120 remain rejected under 35 USC 102(e) for the reasons previously set forth in Paper No. 17, Section 8, pages 7-11.

Applicant argues that (a) upregulated fibronectin expression is associated with in vivo angiogenesis and submits new evidence that demonstrates that upregulated fibronectin expression is associated with in vivo angiogenesis, (b) Applicant reiterates and incorporates previous arguments. The arguments have been considered but have not been found persuasive because (a') the evidence presented is not drawn to the antagonist of US Patent No. 5,922,676 which is superfibronectin which is clearly demonstrated to inhibit angiogenesis, (b') the arguments are not

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persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

9. Claims 1-3, 9-13, 55, 57-63, 65, 66, 71-72, 75 and 80-97, 100-106, 108-117, 119-120 remain rejected under 35 USC 102(e) for the reasons previously set forth in Paper No. 17, Section 9, pages 11-12.

Applicant (a) reiterates previous arguments and incorporates prior arguments and evidence. The arguments have been considered but have not been found persuasive for the reasons previously set forth. Further applicant argues that Pasqualini et al does not disclose that sFN induces endothelial cell apoptosis. It is noted that this limitation is not recited in any of the rejected claims. Applicant's arguments have not been found persuasive and the rejection is maintained.

10. Claims 80-106, 108-117, 119-120 remain rejected under 35 USC 102(e) for the reasons previously set forth in Paper No. 17, Section 10, page 12.

Applicant argues that (a) Pytela et al's disclosure does not add to the deficient disclosures for the reasons disclosed *supra*, (b) Pytela et al relates to fibronectin not sFN thus anticipation is not established, (c) Applicant incorporates herein previous arguments and evidence. The arguments have been considered but have not been found persuasive (a') for the reasons set forth previously and above, (b') Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to

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patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981), (c') the arguments and evidence are not convincing for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

11. Claims 1-5, 9-13, 19-20, 55-72, 75, 80-106, 108-117, 119-120 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 17 Section 11, pages 12-16.

Applicant argues that none of the cited references disclose that sFN induces endothelial cell apoptosis. The argument has been considered but has not been found persuasive because none of the rejected claims are drawn to this limitation.

Applicant reiterates arguments drawn to sFN as an "alpha5B1 antagonist" and reiterates prior arguments and evidence. The arguments and evidence have been considered but are not found persuasive for the reasons previously set forth.

Applicant incorporates and reiterates arguments drawn to lack of motivation, reasonable expectation of success and motivation to combine. The arguments have been considered but are not found persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

12. Claims 1-5, 9-14, 19-20, 55-72, 75, 80-120 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 17, Section 12, page 17.

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Applicant reiterates arguments made *supra*. The arguments have been considered but have not been found persuasive for the reasons set forth previously and above.

Applicant incorporates prior arguments and evidence. The arguments have been considered but have not been found persuasive for the reasons set forth previously and above.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

13. Claims 121-123 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antagonist that induces endothelial cell apoptosis and interferes with specific binding of the alpha5B1 integrin has no clear support in the specification and the claims as originally filed. A review of the specification did not reveal support for the newly added limitation. The subject matter claimed in claims 121-123 broadens the scope of the invention as originally disclosed in the specification. Applicant is invited to point to page and line number where support for the newly added limitation may be found.

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
February 20, 2003